K081302

510(K) PREMARKET NOTIFICATION SUMMARY

AUG 15 2008

1. Submitter:

Mega'Gen Co., Ltd.
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South Korea
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2. US Agent/Contact:

Kodent Inc.
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Phone: 562-404-8466, Fax: 562-404-2757

3. Date Prepared:

May 5, 2008

4. Device Name:

Rescue External Implant System

5. Device Classification:

Status: Class II
Name: Endosseous Implant and Accessories
Regulation Number: 21 CFR 872.3640 and 21 CFR 872.3630

6. Purpose:

The purpose of this 510(k) is to include the components that are to be used with the external method in joining the fixtures and prosthetics to the prior 510(k) submission for the Rescue External Implant System.

7. Intended Use:

Rescue External Implant System consists of machined titanium, screw-form, root-form endosseous dental implants. It is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed.

8. Performance Standards:

FDA has not established a performance standard applicable to endosseous implants. The materials in the Rescue Implant System meet applicable standards.

9. Device Description:

The Rescue External Implant System consists of machined titanium, screw-form, root-form endosseous dental implant. The implants are used to replace missing teeth in various situations ranging from a single missing tooth to the completely edentulous individual. The wide ranges of size are provided to be in conformance with each patient, or to cover up in case of due to deficiency in implant operation. The system is used as two stage, root-form dental implants, associated with abutment systems, which provide the clinician with the screw (for UCLA abutments) and cement (for solid abutments) retained restoration for multi-mount options. Fixtures, the prosthetics, and the surgical instruments are produced and packaged separately. All included devices in the system are covered by this submission.

10. Packing / Labeling / Product Information:

Rescue External Implant System follows the guidance of the 21 CFR 872.3640 and 21 CFR 872.3630.

11. Substantial Equivalence Comparison:

Rescue External Implant System is essentially an addition to the predicate device previously cleared for marketing by FDA, Rescue Dental Implant System (K063216, K053353) and Rescue Internal Implant System (K073058). The noted difference in the design and material does not effectively change the performance of the device and Rescue External Implant System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Megagen Implant Company, Limited
C/O Mr. Jung Bae Bang
Kodent Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K081302
Trade/Device Names: Rescue External Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 24, 2008
Received: July 24, 2008

Dear Mr. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081302

Indication for Use

510(K) Number (if known):

Device Name: Rescue External Implant System

Indications For Use:

The Rescue External Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants are intended to be used where smaller implants have failed.

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081302

Prescription Use X **AND/OR** **Over – The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)